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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,621	04/17/2000	Yuqui Jiang	210121.47005	1408

500 7590 05/09/2002

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/09/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/551,621

Applicant(s)

JIANG ET AL

Examiner

Janet Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period of 3 MONTHS will apply, and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
 - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may, nevertheless, earn patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 13-16, 21-38, 40-43, 48-76 and 80-84 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 13-16, 21-38, 40-43 and 48-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 6 and 80-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) to a provisional application.
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 6, and 80-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record in the rejection of claims 4-5, 7-12, 17-20, 39, 44-47 and 77-79 under 35 USC 112, first paragraph, as set forth in the Official Action mailed 10-09-01.

Applicant's arguments filed 2-12-2002 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that because the claims as amended recite functional language, e.g. "wherein said polynucleotide is over-expressed in breast tissue as compared to normal tissue," Applicants have provided sufficient descriptive information to demonstrate that Applicants were in possession of the claimed invention as per the guidelines for "Written Description" (Federal Register: January 5, 2001, Vol. 66, No. 4, pgs. 1099-1111). However, contrary to Applicant's assertions, Applicant's amendments to the claims do not find adequate support in the specification as filed. For example, Applicants have amended claim 6 to recite "[a]n isolated polynucleotide comprising at least the coding region of a sequence recited in SEQ ID NO:474." There is no clear support for this amendment to the claim, nor has Applicant indicated where support for this amendment can be found in the specification. Secondly, Applicant's specification does not teach that the nucleotide sequence

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according to SEQ ID NO: 474 is over-expressed in breast tissue as compared to normal tissue, as recited in claim 80. The specification as filed provides several examples wherein polynucleotides were over-expressed in breast tissue as compared to normal tissue, however the polynucleotide according to SEQ ID NO: 474 was not so described. According to the specification as filed (page 121, 3rd para.) the B726P cDNA clone (the partial sequence provided in SEQ ID NO: 71) is over expressed in breast tumor tissue as determined by breast cDNA subtraction libraries. The sequence according to SEQ ID NO: 474 was not isolated in this manner, this sequence was found in subsequence studies to identify the full length clone of B726P (SEQ ID NO: 71). The B726P clone was used as a probe to screen a directional cDNA library and a random-primed cDNA library made using DNA isolated from breast tumors. Eighty-five clones were identified, of which three were found to contain a significant open reading frame. After more subsequent studies (the specification does not indicate how the subsequent studies were performed) an additional splice form of B726P was isolated, the determined cDNA sequence of this alternative splice form is disclosed as SEQ ID NO: 474 (page 122, 2nd para.). However, the specification does not indicate that this alternative splice form of the B726P clone is actually over expressed in breast tumor tissue. Therefore, the specification as filed does not provide adequate support for Applicant's amendment to the instant claims. Thus, the functionality added to the instant claims is not sufficient to obviate the instant rejection for lack of written description.

As stated in the prior Official Action, the scope of the instant claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between the genus members are permitted, and neither the specification or the claims

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provide any guidance as to what specific changes should be made. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the claimed genus of polynucleotides, and because the genus is highly variant, the disclosed sequence of SEQ ID NO: 474, alone is not sufficient to describe claimed genus.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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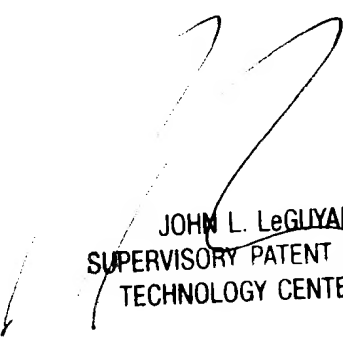
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

jle
May 2, 2002


JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600